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# Development and Validation of Simultaneous Analytical Method for TRYPAZINE Product (Diminazene Diaceturate + Phenazone) by using RP-HPLC Method

A Thesis Submitted in partial Fulfillment of the requirements of the MSc in Industrial Chemistry

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# Dedication

This humble work is dedicated to my Mum the spring of love, kindness.

To whom I have been honoured by the link of my name with his, my Dad may Allah almighty shower his mercy on his soul.

To my supervisor who spare no effort of giving advice and guidance which are without it after Allah's help, this study would have not been achieved.

To my brothers, friends, colleagues and beloved kinship.

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# Abstract

Stability indicating HPLC method has been developed for simultaneous estimation of Diminazene Diaceturate and Phenazone (Antipyrine) in their combined dosage form. For RP-HPLC method, all the standard and sample solution were prepared in water. A RP-HPLC method has been developed and subsequently validated for simultaneous estimation of Diminazene Diaceturate and Phenazone in their combination product. The proposed RP-HPLC method utilizes a C18 25 cm × 4.6 mm, 5um the column, mobile phase consisting of a mixture of (Acetonitrile: Sodium chloride buffer solution) in the proportion of (20: 80) (v/v), and UV detection at 254 nm. the described method was linear over arrange of 50-200 ug/ml with correlation coefficient ($r^2$) of 0.9993 for Diminazine Diaceturate and arrange of 175-700 ug/ml with correlation coefficient ($r^2$) of 0.9996 for Phenazone . Validation of the proposed method were carried out for its accuracy, precision, linearity and range and specificity according to ICH guidelines. A stability indicating study was also carried out and indicated that this method can also be used for purity and degradation evaluation of these formulations that occurred due to temperature, humidity and time.

The method has been successfully applied for these analysis of drugs in formulation.

# مستخلص البحث


تم في هذه الدراسة تطوير وتحقق من طريقة تحليل في آن واحد لعقاري دايمينازين (Diminazene) وفينازون (Phenazone) اللذان تم تركيبهما في شكل حقن باستخدام جهاز الكروماتوغرافيا السائله عالية الاداء.

وتم تحضيرالمادة القياسية والعينات باستخدام الماء كمذيب. كما تم اجراء عملية الفصل الكروماتوغرافي باستخدام عمود فصل معكوس الطبقه الثابته من النوع C18 بمواصفات (25سم×4.6ملم,5 ميكروميتر) وطور متحرك mobile phase يتكون من اسيتونيتريل (Acetonitrile) ومحلول كلوريد الصوديوم بنسب هي 80:20 علي التوالي كما تم القياس بواسطة الاشعة فوق البنفسجية علي طول الموجة 254 نانوميتر.

أعطت الطريقة منحنى خطياً علي مدى التراكيز من 25 - 100 ميكروجرام/مل وبمعامل ارتباط مقداره 0.9993 بالنسبه لعقار دايمينازين (Diminazene), ومنحنى خطياً أيضاً علي مدى التراكيز من 175 - 700 ميكروجرام/مل وبمعامل ارتباط مقداره 0.9996 بالنسبة لعقار فينازون (Phenazone).

تم التحقق من الطريقه المقترحه باجراء اختبارات صحة القراءات (accuracy) ودقتها (precision) والعلاقه الخطيه للطريقه ومداها (linearity & range) واختبار انتقائية الطريقه للعقار(specificity) وكل تلك الاختبارات تمت وفقاً لدليل التحقق من طرق التحليل المبتكرة .(ICH guideline)

كما تم اجراء الدراسه التي تشير الي استقرار العقار والتي بينت ان الطريقه يمكن ان تستخدم لاختبار القاء(Purity) وتقييم تحطم العقار الذي ينجم بفعل الحرارة,الرطوبه والزمن أي انها طريقة تشير للإستقرار (Stability indicating method).

تم استخدام الطريقه في تحليل الدواء المركب في شكل حقن بنجاح.